

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-1
	Transmittal Letter DME- <del>1920</del>	Date <del>11/01/00</del> 08/01/08

#### 409.401: Introduction

~~The regulations in~~ 130 CMR 409.000 ~~describes~~state the requirements for the purchase, rental, and repair of durable medical equipment (~~DME~~), and for the purchase of medical/~~surgical~~ supplies under MassHealth. All durable medical equipment and supplies (DME) must be of proven quality and dependability, and must conform to all applicable federal and state product standards. All DME providers participating in MassHealth must comply with MassHealth regulations at 130 CMR 409.000 and 450.000 ~~durable medical equipment and medical/surgical supplies must be of proven quality and dependability, and must conform to all applicable federal and state product standards. MassHealth may deny or terminate enrollment as a MassHealth DME provider if the provider or applicant does not meet any of the criteria below.~~

#### 409.402: Definitions

The following terms used in 130 CMR 409.000 have the meanings given in 130 CMR 409.402 unless the context clearly requires a different meaning. ~~The reimbursability of~~ Payment for services defined in 130 CMR 409.402 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 409.000, and in 130 CMR 450.000.

Absorbent Products — diapers or brief-like garments, underpads, liners, and shields used to contain and/or manage symptoms of incontinence. Absorbent products may be disposable, reusable, or washable.

Accessories ~~Equipment~~ — products that are fabricated primarily and customarily to modify or enhance the usefulness or functional capability of another piece of equipment and that are generally not useful in the absence of that other piece of equipment.

Adjusted Acquisition Cost — ~~(1) except where the manufacturer is the provider, the price~~the adjusted acquisition cost is the actual amount paid by the provider to the manufacturer or any other supplier ~~for of DME, excluding all associated costs~~ customized equipment, or medical/surgical supplies, excluding all associated costs such as, ~~but not limited to,~~ shipping, handling, and insurance in accordance with the regulations of the Division of Health Care Finance and Policy (DHCFP) costs; and (2) wWhere the manufacturer is the provider, the adjusted acquisition ~~actual cost~~ is the actual cost of manufacturing such DME ~~or supplies~~.

Agent — the person who has been delegated by the applicant or provider the authority to obligate or act on behalf of a provider or applicant.

Ambulatory Equipment — products that provide stability and security for patients with impaired ambulation.

Applicant — An organization or individual who completes and submits an application to become a provider for MassHealth, but has not yet been determined by the MassHealth agency to be eligible to become a provider.

Augmentative and Alternative Communication Devices (AAC) — speech and communication aids that meet the functional speaking needs of members for whom such devices are medically necessary.

Compression Devices — products that are used for the treatment of lymphedema or chronic venous insufficiency with venous stasis ulcers.

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-2
	Transmittal Letter DME- <del>4920</del>	Date <del>11/01/00</del> 08/01/08

CORI — Criminal Offender Record Information — The body of Massachusetts criminal records information that is kept by the Commonwealth of Massachusetts in the Probation Central File, data which is presided over by the Criminal History Systems Board (CHSB) located in the state of Massachusetts.

Customized Equipment — ~~DME~~ durable medical equipment that:

- (1) is uniquely constructed or substantially modified for a specific member;
- (2) is made to order or adapted to meet the specific needs of an individual; and;
- (3) is sufficiently specialized or modified to preclude the use of such equipment by another individual.  
~~is made to order or adapted to meet the specific needs of a particular patient and that is sufficiently specialized or modified to preclude the use of such equipment by subsequent patients.~~
- (1) Custom Fabricated — the equipment in question has been made for the patient from measurement and/or patterns only.
  - (a) Molded to Patient Model — a plaster cast of the involved portion of the patient's body from which a positive cast is then developed. This positive mold represents the patient model from which the ultimate equipment is fabricated.
  - (b) Non-molded — no casting or molding techniques used in the fabrication of the equipment in question. The equipment can be a stock item or can be made from measurement and/or patterns only.
- (2) Custom Fitted — no casting or molding techniques in the fabrication of the equipment in question.

Date of Service — The date the DME is delivered to or picked up by the member, with the exception of 130 CMR 409.419 (C).

Designee — a person designated by the member who can sign and accept the delivery of DME on behalf of the member.

DME — Durable Medical Equipment and Medical Supplies

DME Provider — an organization or individual that has enrolled with MassHealth and has signed a provider contract with the MassHealth agency in accordance with 130 CMR 409.404 and 130 CMR 450.000.

Durable Medical Equipment — ~~products~~ equipment that:

- (1) ~~are~~ is fabricated primarily and customarily to fulfill a medical purpose;
- (2) ~~are~~ is generally not useful in the absence of illness or injury;
- (3) can withstand repeated use over an extended period; and
- (4) ~~are~~ is appropriate for use in the member's home-use.

Eligible Provider — any person, partnership, corporation, or other entity authorized by the Division to engage in the business of furnishing DME, medical/surgical supplies, or customized equipment, and who meets such conditions of participation as may be adopted by a government unit.

Emergency Service — a serious situation, such as a medical crisis, that arises suddenly and threatens the life or welfare of a person.

Licensed Physician — a physician licensed by the Massachusetts Board of Registration in Medicine or by the appropriate board of registration in the state in which the physician practices.

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-3
	Transmittal Letter DME- <del>1920</del>	Date <del>11/01/00</del> 08/01/08

Enteral Nutrition — nutrition requirements that are provided via the gastrointestinal cavity by mouth (orally) or through a tube or stoma that delivers the nutrients distal to the oral cavity.

Glucose Monitor — a device for measuring blood glucose levels.

Home — for purposes of rental and purchase of DME, a member's home may be the member's own dwelling, an apartment, a relative's home in which the member resides, a rest home, or another type of group residence.

Home Infusion Therapy (HIT) Services — the administration of medications to a member in a home setting using delivery devices through intravenous, subcutaneous, or epidural routes. Drug therapies commonly administered include antibiotics, chemotherapy, pain management, parenteral nutrition, and immune globulin.

Medical/~~Surgical~~ Supplies — consumable or disposable supplies or devices for home use necessary for the treatment of a specific illness, injury, disease, or disability, including, but not limited to test strips, syringes, ostomy products, and surgical items ~~medical/treatment products~~ that are:

- (1) ~~are~~ fabricated primarily and customarily to fulfill a medical ~~or surgical~~ purpose;
- (2) ~~are~~ used in the treatment of a specific medical condition;
- (3) ~~are~~ generally not useful in the absence of illness or injury; ~~and~~
- (4) ~~are~~ non-reusable and disposable; ~~and~~
- (5) appropriate for use in the member's home.

Mobility System — ~~any~~ manual or motorized wheelchair or other wheeled device, such as a scooter, including its components, accessories, and modifications, ~~that is prescribed by a physician.~~

Nurse Practitioner — a registered nurse who has successfully completed a formal education program for nurse practitioners as required by the Massachusetts Board of Registration of Nursing (the Board), who is in good standing with the Board, and who is responsible for oversight of the member's health care. A nurse practitioner who prescribes medication must be certified by the federal Drug Enforcement Agency (DEA).

Nutritional Supplements — commercially-prepared products, the primary purpose of which is treatment for a diagnosed deficiency in the member's diet or nutrition.

Ostomy Supplies — products used to divert urine or fecal contents outside the body for patients who have a surgically created opening (stoma).

Parenteral Nutrition — nutrient requirements provided by means of a subcutaneous or intravenous route.

Personal Emergency Response System (PERS) — an electronic device ~~hooked~~ connected to a person's telephone line. In an emergency, it can be activated either by pushing a small button on a pendant, pressing the help button on the console unit, or by an adaptive switch set-up. When the device is activated, a person from the 24-hour-a-day, seven-day-a week central monitoring station answers the call, speaks to the ~~patient member~~ via the console unit, assesses the need for help, and takes appropriate action. ~~A medical communication system qualifies as a PERS if it includes all four of the following requirements:~~

- (1) ~~an in-home medical communications transceiver;~~

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-4
	Transmittal Letter DME- <del>1920</del>	Date <del>11/01/00</del> 08/01/08

~~(2) a remote, portable activator;~~  
~~(3) a central monitoring station with backup systems staffed by trained attendants 24 hours a day, seven days a week; and~~  
~~(4) current data files at the central monitoring station containing preestablished response protocols and personal, medical, and emergency information for each client.~~

Physician Assistant — a mid-level medical practitioner who works under the supervision of a licensed physician (MD) or osteopathic physician (DO) and who has graduated from an accredited physician assistant program and is certified by and in good standing with the Massachusetts Board of Physician Assistant Registration.

Prescribing Provider — the member's physician, nurse practitioner, or physician assistant who prescribes and writes the prescription for DME in accordance with 130 CMR 409.416.

Prior Authorization (PA) Request — a request submitted by the DME provider to the MassHealth agency to determine medical necessity in accordance with 130 CMR 409.417, 130 CMR 409.418, 130 CMR 450.204, and 130 CMR 450.303.

Rehabilitation Technology Supplier (RTS) — an individual with experience in assistive/rehabilitation technology in the areas of wheeled mobility, seating and alternative positioning, ambulation assistance, environmental control, and/or products of daily living. The RTS must possess knowledge of the standards of acceptable practice in the provision of DME, including ordering, assembling, adjusting, delivering, and providing ongoing support and service to meet the member's rehabilitation equipment needs. The RTS must be certified by the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA), as an Assistive Technology Practitioner (ATP), an Assistive Technology Supplier (ATS), or a Rehabilitation Engineering Technologist (RET).

Seating and Mobility (or Wheelchair) Clinic — a clinic held at a facility such as a hospital or rehabilitation center where the rehabilitation technology supplier and the member meet with a physician and physical or occupational therapist, each of whom has expertise in equipment provision, to determine and prescribe the most appropriate seating and/or mobility system or wheelchair to meet the medical needs of the member.

Seating System — a seated positioning system, including its components, accessories, and modifications, designed to meet the individualized medical needs of a member.

Service Facility — a DME business or branch of a DME business where MassHealth members can obtain services, equipment, and supplies, including, but not limited to, especially repairs, or replacements, or accessories, can be obtained, and that is accessible to MassHealth members.

Special Adaptive Mobility System — a mobility system ~~wheelchair or a scooter that is of the type classified as K0004 through K0014 or E1230 in Subchapter 6 of the Durable Medical Equipment Manual and~~ that is customized for the personal full-time use of a member residing in a nursing facility.

Special Adaptive Mobility System Add-On — a customized accessory part that is of the type classified as K0015 through K0109 in Subchapter 6 of the Durable Medical Equipment Manual that

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-5
	Transmittal Letter DME- <del>1920</del>	Date <del>09/19/98</del> 08/01/08

may be added on to a base standard or customized wheelchair mobility system and that is for the personal full-time use of a member residing in a nursing facility.

Support Surfaces — beds, mattresses, or overlays used to reduce or relieve pressure, prevent the worsening of pressure ulcers, or promote wound healing.

#### 409.403: Eligible Members

(A) MassHealth Members. ~~The Division~~ MassHealth covers DME services provided to eligible MassHealth members, subject to the restrictions and limitations described in ~~the Division's~~ MassHealth regulations. ~~The Division's MassHealth~~ regulations at 130 CMR 450.105 specifically state, for each coverage type, which services are ~~describe the services covered, and which~~ and the members are eligible to receive those services under each coverage type.

(B) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(C) Verification of Member Eligibility. For information about verifying member eligibility and coverage type, see 130 CMR 450.107.

#### 409.404: Provider Eligibility

~~Payment for services described in 130 CMR 409.000 is will be made only to providers of DME, DME repair services, or medical supplies who are participating in MassHealth as a DME provider or have been assigned a DME specialty in accordance with 130 CMR 409.404(C) as of the date of service. Applicants must meet the requirements in 130 CMR 450.000 as well as the requirements in 130 CMR 409.000. Participating providers must continue to meet provider eligibility participation requirements throughout the period of their provider contract with the MassHealth agency. In addition, the following eligibility requirements must be met.~~

(A) ~~In State.~~ All applicants must submit a letter of intent prior to receiving and completing a MassHealth provider application for DME. The letter of intent must describe:

- (1) the applicant's primary scope of business, including which DME services and products the applicant intends to provide;
- (2) a list of any subcontractors the applicant intends to use and for what purpose;
- (3) existing contacts with other payers, and
- (4) service area(s) in which services will be provided.

(B) General. To qualify as a MassHealth DME provider, all applicants and providers must:

- (1) A provider located in Massachusetts must primarily engage in the business of providing DME, DME repair services, or medical supplies to the public and meet all state and local requirements for engaging in such a business.
- (2) A provider of DME, DME repair services, or medical supplies must have a service facility, as defined at 130 CMR 409.402 in the Commonwealth of Massachusetts, that:
  - (a) is available to members, during regular, posted business hours;
  - (b) is physically accessible to members with disabilities;
  - (c) has clear access and space for individualized ordering, returns, repair, and storing of business records;
  - (d) has a sign visible from outside of the facility identifying the business name and hours that the service facility is open. If the provider's place of business is located within a

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-6
	Transmittal Letter DME- <del>1920</del>	Date <del>09/19/98</del> 08/01/08

- building complex, the sign must be visible at the main entrance of the building where the place of business is located;
- (e) has a primary business telephone number listed in the name of the business with a local toll-free telephone number that is answered by customer service staff during business hours. During business hours, this number cannot transfer to an out-of-state number, and cannot be a pager, answering machine, answering service, or cell phone.
- (2) except for specialty providers described in 130 CMR 409.22. 404(CB), primarily engage in the business of providing DME, or DME repair services, to the public;
- (3) participate in the Medicare program as a DME provider, unless the provider solely supplies PERS;
- (4) have a Medicare provider number that is assigned to the same business and service facility and location for which the applicant or provider is applying to become a MassHealth provider;
- (5) be accredited by an accrediting body, acceptable to the Centers for Medicare and Medicaid Services;
- (6) meet all applicable federal, state, and local requirements, certifications, and registrations;
- (7) at the time of application and re-credentialing, or any other time as requested by the MassHealth agency, provide all required documentation specified in 130 CMR 450.000 and:
- (a) a list of contracted manufacturers used for purchased products
- (b) a copy of all current liability insurance policies;
- (c) a copy of the property lease agreement pertinent to the service facility, or a copy of the most recent property tax bill if applicant owns the business site.
- (d) a copy of current RESNA Certificate (mobility providers only);
- (e) a copy of all current signed employee professional licenses, as applicable;
- (f) a copy of current accreditation letters
- (g) a copy of the purchase and sale agreement if the provider or applicant has recently purchased the company for which they are applying to become a MassHealth provider.
- (h) a copy of subcontracts, if applicable, as described in 130 CMR 409.412. For PERS providers, the subcontract must include the central monitoring station contract, if applicable.
- (i) a copy of the applicant's emergency preparedness plan as approved by the accrediting body; and
- (j) a copy of written policies and procedures, including: the service facility customer service protocol; customer complaint tracking and resolution protocol; and staff training.
- (8) for a provider of home infusion services, be a licensed pharmacy in Massachusetts and be accredited by an accrediting body, as approved by the Centers for Medicare and Medicaid Services, and be assigned a DME specialty by MassHealth. See 130 CMR 409.404(C).
- (9) conduct CORI checks on all employees or subcontractors where the employee or subcontractor delivers or sets up equipment in a member's home;
- (10) not accept prescriptions for MassHealth DME from any prescribing provider who has a financial interest in the DME provider; and
- (11) cooperate with the MassHealth agency or its designee during the application and re-credentialing process, including participation in a site visit.

- (C) Providers assigned DME specialty: Applicants and providers whose primary business is not DME as described in 130 CMR 409.404(A) may qualify to provide DME services if the following conditions are met:
- (1) the applicant is enrolled as a MassHealth provider of Oxygen and Respiratory services under 130 CMR 427.000 or Pharmacy services under 130 CMR 406.000;



Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-7
	Transmittal Letter DME- <del>1920</del>	Date <del>09/19/98</del> 08/01/08

(2) the applicant meets all other conditions under 130 CMR 409.404 to provide DME services;

(3) MassHealth has assigned a specialty of DME to the applicant's existing provider number for Oxygen/Respiratory or Pharmacy.

(D) In State. To qualify as an in-state provider of DME, the applicant or provider must have a service facility located in Massachusetts that meets the criteria described in 130 CMR 409.404(A).

~~(BE) Out of State of State. A provider located~~An applicant or provider of DME with a service facility located outside of Massachusetts is eligible to participate in the MassHealth DME program only if he or she may qualify as a MassHealth DME provider if the following conditions are met:

- (1) all requirements under 130 CMR 409.000 and 130 CMR 450.000 are met; participates in the medical assistance program (or the equivalent) of the state in which the provider primarily conducts business;
  - (2) primarily engages in the business of providing DME, DME repair services, or medical supplies to the public and meets all of their state and local requirements for engaging in such a business; and the DME provider participates in the Medicaid program of the state in which the provider primarily conducts business, unless the DME provider solely provides PERS;
  - (3) the DME provider participates in the Medicare program of the state in which the provider primarily conducts business, unless the DME provider solely provides PERS; and
  - (34) has a service facility as described in 130 CMR 409.402, within 50 miles of the Massachusetts border.the provider has a service facility that can readily replace and repair products when needed by the member.
- and providers

#### 409.405: Provider Responsibilities

In addition to meeting all other provider requirements set forth in 130 CMR 409.000 and 450.000, the provider must:

(A) accept rates of payment established by the Division of Health Care Finance and Policy (DHCFP) for all DME provided to MassHealth members, unless otherwise determined by the MassHealth agency through a contracting process or by other means.

(B) notify the MassHealth agency in writing within 14 days of any changes in any of the information submitted in the provider application in accordance with 130 CMR 450.223(B), including but not limited to, change of ownership, change of address, and additional service locations. The provider must maintain records of all such communications and transactions and make such records available to the MassHealth agency for review upon request.

(C) ensure that the DME provided is the most cost-effective, given the medical need for which the DME is prescribed and the member's limitations;

(D) purchase the item from the least costly reliable source;

(E) fill all orders from its own inventory or have a written subcontract for the purchase of items necessary to fill orders in accordance with 130 CMR 409.412;

(F) comply with MassHealth administrative and billing regulations at 130 CMR 450.000;

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-8
	Transmittal Letter DME- <del>1920</del>	Date <del>09/19/98</del> 08/01/08

(G) report to the proper authorities any suspected abuse or neglect that staff may observe when providing service to a member;

(H) provide employees a picture identification to be presented to a member when making a delivery;

(I) adhere to the Supplier Standards set forth by the Center for Medicare and Medicaid Services (CMS);

(J) not alter any invoice or medical documentation;

(K) not solicit members to purchase additional DME

(L) submit prior authorization requests to MassHealth when DME is medically necessary and when prior authorization is a prerequisite. See 130 CMR 409.418.

(M) respond within one business day to members' complaints regarding their DME.

(N) not share a practice location with another provider of DME, including a physician/physician group or another supplier of DME.

(O) 409.405 DME providers who change their primary scope of business and will no longer provide the scope of DME services and products that were provided at the time MassHealth approved the DME application must provide MassHealth and members with written notification at least 60 days in advance. Notification to the member must include:

1. a list of DME providers who can provide the service in the member's area; and
2. if prior authorization is required for the service;
  - a. the number of non billed units remaining on the PA
  - b. a copy of the original PA approval from MassHealth for the member to provide to the new DME provider.

#### 409.4056: Services Provided to Members in Another State Durable Medical Equipment, Repair Services, and Medical Supplies Members Provided by Eligible Out-of-State Providers

The MassHealth agency pays for DME provided to MassHealth members in another state by a MassHealth DME provider in accordance with 42 CFR 431.52(b) and 130 CMR 450.109. In accordance with 42 CFR 431.52(b), the Division covers services furnished in another state by a provider as described at 130 CMR 409.404(B) to the same extent that it would cover services within its boundaries by a provider as described at 130 CMR 409.404(A) if the services are furnished to a member who is a resident of Massachusetts. However, if the provider's service facility is beyond the 50-mile limit described in 130 CMR 409.404(B)(3), the Division will pay for services only where one of the following conditions is met:

(A) services are needed because of a medical emergency as described in 130 CMR 409.402;

(B) medical services are needed and the member's health would be endangered if he or she were required to travel to his or her state of residence;

(C) the Division determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other state; or



Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-9
	Transmittal Letter DME- <del>2019</del>	Date <del>09/19/98</del> 08/01/08

~~(D) it is general practice for members in a particular locality to use medical resources in another state.~~

#### 409.406: Nonreimbursable Services

~~(A) The Division does not pay for DME or medical/surgical supplies that are experimental in nature, unless the provider has obtained prior authorization from the Division.~~

~~(B) The Division does not pay for nonmedical equipment or supplies. Equipment that is used primarily and customarily for a nonmedical purpose is not considered medical equipment, even if such equipment has a medically related use. Medical equipment and supplies must meet the requirements set forth in 130 CMR 409.402.~~

~~(C) The Division does not pay for DME or medical/surgical supplies that are not, in its determination, both necessary and reasonable for the treatment of a member's medical condition. This includes, but is not limited to:~~

- ~~(1) items that cannot reasonably be expected to make a meaningful contribution to the treatment of a member's illness or injury;~~
- ~~(2) items that are substantially more costly than medically appropriate and feasible alternative pieces of equipment; or~~
- ~~(3) items that serve the same purpose as those items already in use by the member.~~

~~(D) The Division does not pay for accessory equipment unless the item for which the equipment is an accessory is reimbursable under these regulations. If the item for which the accessory equipment is required was not purchased by the Division, the Division may request a physician's prescription, pursuant to 130 CMR 409.407, to justify the need for the item.~~

~~(E) The Division does not pay for the repair of any equipment unless such equipment is reimbursable under these regulations.~~

~~(F) The Division does not pay for routine periodic testing, cleaning, regulating, and checking of equipment. This limitation does not apply to extensive maintenance that, based on the manufacturer's recommendations, must be performed by authorized technicians. Such extensive maintenance is considered a repair service and is reimbursable under 130 CMR 409.425.~~

~~(G) The Division does not pay a DME provider for the evaluation or diagnostic test used to establish the medical need for durable medical equipment or associated supplies.~~

(130 CMR 409.407 through 409.411 Reserved)

#### 409.407: Prescription Requirements

~~(A) The rental or purchase of DME and the purchase of medical/surgical supplies are reimbursable only after the provider has obtained a written prescription signed by a licensed physician or nurse practitioner. The prescription must be dated within 90 days of the requested date of service (which is the initial date of service requested in the prior authorization request), or within 90 days of the date the prior authorization request is received by the Division if prior authorization is required, whichever is longer. The prescription must contain the following information:~~

- ~~(1) the member's name and address;~~
- ~~(2) specific identification of the prescribed item;~~
- ~~(3) medical necessity criteria for the use of the item (including the diagnosis and disabling condition);~~
- ~~(4) the estimated length of time that the item will be used by the member;~~

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-10
	Transmittal Letter DME- <del>1920</del>	Date <del>09/19/98</del> 08/01/08

- ~~(5) the location in which the member will customarily use the item;~~  
~~(6) the prescriber's address and telephone number; and~~  
~~(7) the date on which the prescription was signed by the prescriber. \_\_\_\_\_~~

~~(B) The prescription must be written on the prescriber's prescription pad, the prescriber's letterhead stationery, or a Region A Durable Medical Equipment Regional Carrier (DMERC) certificate of medical necessity. If the Region A DMERC certificate of medical necessity is used, it must be completed in accordance with the instructions established by the Region A DMERC, in addition to complying with these regulations.~~

~~\_\_\_\_\_ (C) The provider must keep the physician's prescription on file for a minimum of four years following the date of service.~~

#### ~~409.408 Prior Authorization~~

~~\_\_\_\_\_ (A) The provider must obtain prior authorization as a prerequisite for payment for DME, medical/surgical supplies, or services listed in 130 CMR 409.409 and 409.410, except as specified in 130 CMR 409.431(B). Prior authorization does not waive any other prerequisites for payment including, but not limited to, requirements relating to member eligibility or resort to health insurance payment.~~

~~(B) All prior authorization requests must be submitted in accordance with the instructions in Subchapter 5 of the *Durable Medical Equipment Manual*. Before determining the medical necessity of an item for which prior authorization is requested, the Division may, at its discretion, require an evaluation by a registered physical therapist or another health care professional who has expertise in equipment provision, to determine whether the requested item will meet stated medical and functional needs, given the member's physical condition and the physical environment in which the item will be used.~~

~~\_\_\_\_\_ (C) An invoice that reflects the provider's adjusted acquisition costs according to regulations found at 130 CMR 409.420 must be included with the prior authorization request for each item.~~

~~\_\_\_\_\_ (D) Manufacturers who provide services must submit documentation that demonstrates, to the Division's satisfaction, the cost of manufacturing the item provided, as described in 130 CMR 409.420(D).~~

~~\_\_\_\_\_ (E) The provider must submit the request for prior authorization within 90 days of the requested date of service (date of delivery) or within 90 days after the prescription is generated. Failure to submit the request within the 90-day period will result in a denial of payment.~~

~~(F) Written notification of the prior authorization decision will be sent to the member and the provider, and will indicate approval, modification, or denial. Deferrals will be sent back to the provider with a reason for the deferral and an opportunity to resubmit. The provider is responsible for explaining the deferral reason to the member. Notification of denial will include the reason for the denial. The provider has the right to resubmit additional information, as does the member or the prescriber, through the provider. The member may appeal the denial of a prior authorization request within 30 days after the date of the notice of denial. Procedures for such an appeal are set forth in 130 CMR 610.000.~~

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-11
	Transmittal Letter DME- <del>19</del> <u>20</u>	Date <del>11/01/00</del> 08/01/08

~~(G) The Division will take no longer than 15 days after the date of receipt to decide on a prior authorization request. The Division will confirm the date of receipt and the date of the decision upon written request. If, after 15 days, the Division is notified that it has not yet acted on a prior authorization request, the Division will so act within 24 hours of receiving such notice. When, in the event of an emergency medical need, the 15-day period to act would jeopardize the member's health, a prior authorization request may be made by telephone to the Division's Prior Authorization Unit. If authorization is granted, a prior authorization number will be given by telephone, and a written follow-up will be sent upon receipt of the required documentation from the provider.~~

#### ~~409.409: Purchases Requiring Prior Authorization~~

- ~~(A) The purchase of any of the following equipment requires prior authorization:~~
- ~~(1) manual or electric hospital bed systems;~~
  - ~~(2) hospital bed accessories, including mattresses;~~
  - ~~(3) standard transport devices, including patient lifts;~~
  - ~~(4) manual or electric mobility systems, including wheelchairs;~~
  - ~~(5) decubitus care apparatus, including alternating pressure pads and pumps;~~
  - ~~(6) all items listed in Subchapter 6 of the *Durable Medical Equipment Manual* that are indicated as needing prior authorization ("P.A."); and~~
  - ~~(7) all items that are not listed in Subchapter 6 of the *Durable Medical Equipment Manual* whose price totals more than \$25.00.~~

~~(B) The provider must inform the Division when the requested item is to replace equipment currently rented or previously purchased by the Division.~~

#### ~~409.410: Rentals Requiring Prior Authorization~~

~~\_\_\_\_\_ The rental of any of the following requires prior authorization:~~

- ~~\_\_\_\_\_ (A) manual hospital bed systems listed as rental equipment in Subchapter 6 of the *Durable Medical Equipment Manual*;~~
- ~~\_\_\_\_\_ (B) electric hospital bed systems;~~
- ~~\_\_\_\_\_ (C) standard transport devices, including patient lifts;~~
- ~~\_\_\_\_\_ (D) manual mobility systems, including wheelchairs, listed as rental equipment in Subchapter 6 of the *Durable Medical Equipment Manual*, after a rental period of three months;~~
- ~~\_\_\_\_\_ (E) electric mobility systems, including wheelchairs;~~
- ~~\_\_\_\_\_ (F) personal emergency response systems (PERS) as defined in 130 CMR 409.402 (see Subchapter 6 of the *Durable Medical Equipment Manual*); and~~
- ~~\_\_\_\_\_ (G) all equipment that is not listed as rental equipment in the DME list in Subchapter 6 of the *Durable Medical Equipment Manual*.~~

~~(130 CMR 409.411 through 409.419 Reserved)~~

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-12
	<b>Transmittal Letter</b> DME- <del>19</del> <u>20</u>	<b>Date</b> <del>11/01/00</del> 08/01/08

#### 409.412: Subcontracted Services

(A) A DME provider may subcontract with other entities to provide DME. The DME provider continues to be responsible for complying with 130 CMR 450.000 and 130 CMR 409.000 when activities are performed by a subcontractor. The subcontract must be in writing and must contain, at a minimum, the following:

- (1) names, addresses, phone numbers, and contact names for both companies;
- (2) the contract term (begin and end dates);
- (3) a description of the DME covered under the subcontract, including the cost of each item;
- (4) signatures of both parties, including signature dates and position titles;
- (5) an established credit limit that is reasonable, based on the value of the products and services to be provided by the contractor. Collect on delivery (COD) terms are not acceptable;
- (6) provisions requiring the subcontractor to meet all provider participation requirements under 130 CMR 409.404 and 409.405.

(B) A subcontractor of DME must meet all provider requirements under 130 CMR 409.404 and 409.405.

#### 409.413: Covered Services

(A) MassHealth covers DME that can be appropriately used in the member's home and in certain circumstances described in 130 CMR 409.415 for use in facilities. All DME must be approved for home use by the federal Food and Drug Administration (FDA). DME that is appropriate for use in the member's home may also be used in the community.

(B) MassHealth covers the DME listed in Subchapter 6 of the *Durable Medical Equipment Manual*. Providers may request a prior authorization for medically necessary DME if the corresponding code is not listed in Subchapter 6. Covered DME includes, but is not limited to:

- (1) absorbent products
- (2) ambulatory equipment, such as crutches and canes
- (3) compression devices
- (4) speech augmentative devices
- (5) enteral and parenteral nutrition
- (6) nutritional supplements
- (7) home infusion equipment and supplies (pharmacy providers with DME specialty only)
- (8) glucose monitors and diabetic supplies
- (9) mobility equipment and seating systems
- (10) personal emergency response systems (PERS)
- (11) ostomy supplies
- (12) support surfaces
- (13) hospital beds and accessories
- (14) patient lifts
- (15) bath and toilet equipment and supplies (commode, grab bars, tub benches, etc)

(C) MassHealth covers the repair of previously purchased durable medical equipment, subject to the requirements of 130 CMR 409.420.

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-13
	Transmittal Letter DME- <del>1920</del>	Date <del>09/19/98</del> 08/01/08
Durable Medical Equipment Manual		

(D) MassHealth will pay for a manual wheelchair as a backup to a power wheelchair, under the following conditions:

- (1) the level of customization of the primary power wheelchair would preclude the use of a substitute rental wheelchair if the primary wheelchair is removed from the home for repair.
- (2) the member requires frequent outings to a destination that is not accessible to a power wheelchair (for example, stairs without an elevator)
- (3) it is not possible to fit the primary chair in any of the vehicles available to the member for transportation.

(E) MassHealth will pay for a replacement of a member's mobility system only when:

- (1) the cost of repairing the current mobility system will exceed the value of the current system; or
- (2) the member's physical condition has changed enough to render the current mobility system ineffective; and
- (3) the DME provider has obtained prior authorization.

#### 409.414: Non-covered Services

MassHealth does not pay for:

(A) Durable Medical Equipment that is experimental in nature;

(B) DME provided to a member while the member is an inpatient of a hospital, including a chronic disease and rehabilitation hospital (See 130 CMR 409.419(C) about DME provided to members being discharged from inpatient facilities.);

(C) DME that is not, in the MassHealth agency's determination, medically necessary pursuant to 130 CMR 450.204. This includes, but is not limited to items that:

- (1) cannot reasonably be expected to make a meaningful contribution to the treatment of a member's illness or injury;
- (2) are more costly than medically appropriate and feasible alternative pieces of equipment; or
- (3) serve the same purpose as DME items already in use by the member.

(D) The repair of any durable medical equipment that is not identified as a covered service in Subchapter 6 of the *Durable Medical Equipment Manual*;

(E) The repair of any equipment where the cost of the repair is equal to or more than the cost of purchasing a replacement;

(F) Routine periodic testing, cleaning, regulating, and checking of durable medical equipment. Such routine maintenance is not covered as a separate service but is covered through the established rate for the product;

(G) DME that is not of proven quality and dependability;

(H) DME that has not been approved by the federal Food and Drug Administration (FDA) for home use;

(I) Evaluation or diagnostic tests conducted by the DME provider to establish the medical need for DME;

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-14
	Transmittal Letter DME- <del>1920</del>	Date <del>09/19/98</del> 08/01/08
Durable Medical Equipment Manual		

(J) Equipment whose primary function is environmental control, comfort, or convenience, including, but not limited to air conditioners, high-efficiency particulate air (HEPA) filters, and light boxes;

(K) Common household and personal hygiene items generally used by the public, including, but not limited to, washcloths, wet wipes, and non-sterile swabs.

(L) Home or vehicle modifications, such as ramps, elevators, or stair lifts.

#### 409.415: DME Provided to Members in Facilities

##### (A) Skilled Nursing Facilities.

###### (1) Covered Services.

(a) Customized seating and mobility equipment: the MassHealth agency pays for the purchase, rental, or repair of specialized mobility systems, seating systems, and add-ons, subject to all limitations and conditions of payment in 130 CMR 409.000 and 450.000, when provided for the exclusive full-time use of a member residing in a nursing facility (providing the customization precludes the use of equipment by other individuals in the nursing facility). The nursing facility in which the member resides is responsible for payment to the DME provider for the first \$500 toward the equipment purchase, pursuant to 130 CMR 456.414.;

(b) Support surfaces: MassHealth pays for support surfaces for the exclusive full-time use of a member residing in a nursing facility;

(c) Durable medical equipment for members to be discharged from a nursing facility: The MassHealth agency allows a DME provider to deliver equipment to a nursing facility before the member's scheduled discharge date, for the purpose of teaching the member how to use the equipment, taking measurements, or adjusting equipment to be used in the member's home (see 130 CMR 409.419(B)). The DME provider must document the member's discharge plan and discharge date in the member's record before the equipment is delivered to the nursing facility, and provide such documentation to the MassHealth agency upon request. For equipment delivered to a nursing facility for use by a member after discharge from the facility, the date of service is the date of discharge.

(2) Non-covered Services: The MassHealth agency does not pay for medical supplies, including but not limited to absorbent products, or the purchase, rental, or repair of non-customized durable medical equipment when provided to members residing in a nursing facility.

(B) Hospitals, including Acute, Chronic Disease and Rehabilitation, and psychiatric hospitals. The MassHealth agency does not pay for medical supplies, including but not limited to absorbent products, or the purchase, rental, or repair of durable medical equipment provided to a member who is an inpatient in a hospital, except for DME delivered to the member in accordance with 130 CMR 409.419(C).

##### (C) Intermediate Care Facilities for the Mentally Retarded (ICF/MR).

###### (1) Covered Services.

(a) Customized seating and mobility equipment: the MassHealth agency pays for the purchase, rental, or repair of specialized mobility systems, seating systems, and add-ons, subject to all limitations and conditions of payment in 130 CMR 409.000 and 450.000, when provided for the exclusive full-time use of a member residing in an ICF/MR (if the customization precludes the use of equipment by other individuals in the ICF/MR).

(b) Other customized durable medical equipment: MassHealth pays for other durable medical equipment that is provided for the exclusive full-time use of a member residing in



Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-15
	Transmittal Letter DME- <del>4920</del>	Date <del>11/01/00</del> 08/01/08

an ICF/MR (if the customization precludes the use of equipment by other individuals in the ICF/MR).

(c) Durable medical equipment for members to be discharged from an ICF/MR: The MassHealth agency allows a DME provider to deliver equipment to an ICF/MR, before the member's scheduled discharge date, for the purpose of teaching the member how to use the equipment, taking measurements, or adjusting equipment to be used in the member's home (See 130 CMR 409.419 (B)). The DME provider must document the member's discharge plan and discharge date in the member's record before the equipment is delivered to the ICF/MR, and provide such documentation to the MassHealth agency.

(2) Non-covered-services: The MassHealth agency does not pay a DME provider for medical supplies, including but not limited to absorbent products, or the purchase, rental, or repair of non-customized DME provided to a member residing in an ICF/MR.

#### 409.416: Prescription Requirements

(A) The DME provider must obtain a written prescription, signed by the member's prescribing provider, for the purchase or rental of durable medical equipment and for certain medical supplies. The prescription must be written, signed and dated prior to delivery to the member. The initial and subsequent prescriptions must contain the following information:

- (1) the member's name;
- (2) the date of the prescription;
- (3) the name and quantity of the prescribed item and the number of refills (if appropriate); and
- (4) the signature of the prescribing provider and date signed.

(B) The MassHealth agency accepts written prescriptions in the following formats, provided the requirements of 130 CMR 409.416(A) are met:

- (1) the prescribing provider's prescription pad;
- (2) the prescribing provider's letterhead stationery;
- (3) the hospital or nursing facility prescription pad, if the member is being discharged from a facility;
- (4) the MassHealth agency Documentation of Need for Durable Medical Equipment and Supplies General Prescription form;
- (5) the Region A Durable Medical Equipment Carrier (DME MAC) Certificate of Medical Necessity (CMN) completed in accordance with the instructions established by the Region A DME MAC and in compliance with 130 CMR 409.416(A).

(C) a prescription may be transmitted electronically to the DME provider by the member's prescribing provider in accordance with the MassHealth agency's billing instructions and applicable state and federal law.

(D) Prescriptions for members residing in nursing facilities must include a copy of the current month's order sheet, a copy of the medical justification from the member's nursing facility record, and may include additional documentation necessary to support medical necessity. Additional documentation may include physician progress notes, relevant laboratory or diagnostic test results, and nursing, nutrition, or therapy assignments and notes.

#### 409.417: Medical Necessity Criteria

All DME covered by MassHealth must meet the medical necessity requirements set forth in these regulations, in 130 CMR 450.204, and MassHealth's medical necessity guidelines specific to certain DME viewed on the MassHealth Web site. DME providers must additionally adhere to the

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-16
	Transmittal Letter DME- <del>4920</del>	Date <del>11/01/00</del> 08/01/08

clinical policies developed by the Centers for Medicare and Medicaid Services (CMS) when demonstrating medical necessity for certain DME.

(A) In addition to prescription requirements described in 130 CMR 409.416, DME providers must obtain a letter of medical necessity (LOM) for the purchase and rental of durable medical equipment and medical supplies, which must be signed and dated by the member's prescribing provider. The letter of medical necessity must be provided in one of the following formats:

- (1) the MassHealth Medical Necessity Review form developed by the MassHealth agency must be used for specific products as defined by the MassHealth agency.
- (2) the Region A Durable Medical Equipment Carrier (DME MAC) Certificate of Medical Necessity (CMN) completed in accordance with the instructions established by the Region A DME MAC and in compliance with 130 CMR 409.416(A).
- (3) if there is no MassHealth Medical Necessity Review form for the product(s), the MassHealth agency will accept a letter of medical necessity that includes the following documentation:
  - (a) the member's diagnosis and prognosis, including an indication of whether the diagnosis is a pre-existing condition or a presenting condition;
  - (b) the ICD-9 diagnosis code for which the durable medical equipment or medical supply is being prescribed;
  - (c) a description of the member's medical condition;
  - (d) medical justification for the item(s) being requested;
  - (e) the equipment settings, hours to be used per day, options, or additional features, as they pertain to the equipment;
  - (f) the recommended timetable of the prescribed item or treatment;
  - (g) the expected outcome and/or therapeutic benefit of providing the requested item(s) or treatment;
  - (h) a summary of any previous treatment plan, including outcomes, which were used to treat the diagnosed condition for which the prescribed treatment is being recommended;
  - (i) the prescribing provider's name, address, and signature;
  - (j) the date the prescription was signed by the prescribing provider; and
  - (k) the signature of the member's prescribing provider and the date the LOM was signed.

#### 409.418: Prior Authorization (PA)

The DME provider must obtain prior authorization from the MassHealth agency or its designee as a prerequisite for payment of DME identified in Subchapter 6 of the *Durable Medical Equipment Manual* as requiring prior authorization. Prior authorization does not waive any other prerequisites for payment including, but not limited to, requirements relating to member eligibility or other health insurance payments. All prior authorization requests must be submitted in accordance with Appendix A and Subchapter 5 of the *Durable Medical Equipment Manual*.

#### (A) Documentation of Medical Necessity

- (1) Prior authorization requests submitted by the provider for DME must include:
  - (a) a completed MassHealth Prior Authorization Request form (if request is submitted on paper);
  - (b) a prescription that meets the criteria of 130 CMR 409.416 and a letter of medical necessity that meets the requirements of 130 CMR 409.417::
    - (i) if diagnostic test results are used as a means to document medical necessity, the test results must be interpreted, signed, and dated by a physician, or include documentation from an appropriate health care professional other than the DME provider that supports the need for DME including, but not limited to, physical therapists, speech therapists,

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-17
	Transmittal Letter DME- <del>1920</del>	Date <del>09/19/98</del> 08/01/08

nurses, respiratory therapists, and occupational therapists who have expertise in the applicable area.

(c) for DME that is identified in Subchapter 6 of the *Durable Medical Equipment Manual* as requiring individual consideration (IC), a copy of the original invoice that reflects the provider's adjusted acquisition costs as set forth in the regulations of the Division of Health Care Finance and Policy (DHCFP) at 114.3 CMR 22.00;

(i) If the DME have not been purchased by the provider at the time the prior authorization request is submitted to the MassHealth agency, the DME provider may substitute a quote from the manufacturer reflecting the lowest price of the item. The quote must be on the manufacturer's letterhead and must be addressed to the provider

(ii) for disposable medical supplies, the invoice must be dated within six months of the prior authorization request;

(iii) the MassHealth agency will not accept a printed invoice or order from a manufacturer's website.

(B) The provider must submit the request for prior authorization to the MassHealth agency no later than 45 calendar days from the date of the prescription. Failure to submit the request within the 45-day period may result in a denial of the prior authorization request.

(C) Prior authorization requests for DME units in excess of the maximum allowable units: MassHealth requires prior authorization for certain DME provided to the member if the number of units requested exceeds the maximum units described in Subchapter 6 of the *Durable Medical Equipment Manual*.

(1) The provider must include documentation that supports the medical necessity of the additional units, including requirements under 130 CMR 409.417 and 130 CMR 409.418(A); and

(2) if the PA request is authorized by the MassHealth agency, the provider must submit a separate claim with separate dates of service for the number of units provided that exceeded the maximum allowable units and required prior authorization.

(D) Prior authorization requests for members who have other insurance: For members for whom MassHealth is not the primary insurer and for whom the provider is seeking payment from another insurer, the provider must also request a prior authorization from the MassHealth agency according to the timelines set forth in 130 CMR 409.418, if the provider intends to seek secondary payment from MassHealth.

(E) Repairs of durable medical equipment: Providers must submit a prior authorization request for repairs of durable medical equipment that exceed \$1000 per repair, unless otherwise indicated in the Subchapter 6 of the *Durable Medical Equipment Manual* or unless the repair meets the requirements of 130 CMR 409.418(E)(4).

(1) MassHealth pays for repairs to customized mobility systems and special adaptive mobility systems, including customized back-up systems, when both the member's primary and back-up systems are customized to the extent that no rental equipment would be comparable, and the repair is not covered under the warranty.

(2) In addition to documentation otherwise required in 130 CMR 409.418, the DME provider must submit the following documentation with the prior authorization request:

(a) a description of the customization of the member's mobility systems;

(b) an invoice for the repaired or replaced item;

(c) a work order log with the estimated number of hours the repair will take;

(d) a detailed description of the circumstances that made the repair necessary; and

(e) an explanation as to why the repaired or replaced item is not covered under any warranty.

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-18
	Transmittal Letter DME- <del>4920</del>	Date <del>09/19/98</del> 08/01/08

(3) DME providers must furnish the member with substitute equipment in accordance with 130 CMR 409.420 when a repair service requires removal of the equipment from the member's home.

(4) Providers must submit a prior authorization request for repairs of a member's back up wheelchair if the repair exceeds \$300.

(F) Notice of approval, denial, or modification of a prior authorization request:

(1) If the MassHealth agency approves a prior authorization request for DME, the MassHealth agency will send notice of its decision to the member and the DME provider.

(2) If the MassHealth agency denies or modifies a prior authorization request for DME, the MassHealth agency will send notice of its decision to the member and the DME provider. The notice will state the reason for the denial or modification, and will inform the member of the right to appeal and of the appeal procedure in accordance with 130 CMR 610.000.

(3) If the MassHealth agency defers a prior authorization request due to an incomplete submission or lack of documentation to support medical necessity, the MassHealth agency will notify the member and the DME provider of the deferral, and will inform the DME provider of the reason for the deferral and provide an opportunity for the provider to submit the incomplete or missing documentation.

(a) If the provider does not resubmit the prior authorization within 30 calendar days of the date of the deferral, the MassHealth agency may deny the prior authorization request. The provider will then be required to resubmit a new prior authorization that includes all required documentation.

409.419: Delivery of DME

(A) Delivery to a Member's Home.

(1) The provider must maintain in the member's record a copy of the delivery slip signed by the member or the person accepting delivery on behalf of the member, and dated at the time of delivery. The date of the signature on the delivery slip must be the same as the date of delivery.

(2) A signature stamp may be used by or on behalf of a MassHealth member whose disability inhibits the member's ability to write. A signature stamp may be used only by the member or the member's designee. A signature stamp may not be used by anyone associated with either the provider or the delivery service.

(B) Delivery to a Nursing Facility. The provider must obtain and maintain in the member's record documentation as required in 130 CMR 409.415(A), including documentation from the facility that the equipment will only be used for the member to whom the equipment was delivered. This documentation must be in the form of a facility note signed by the facility nurse or physician. The delivery slip must be signed by the member or a designee from the facility, and otherwise meet the requirements of 130 CMR 409.418(B).

(C) Delivery to a Hospital or Nursing Facility in Anticipation of Discharge. A provider may deliver durable medical equipment to a facility for a member who is being discharged from a hospital or nursing facility for the purpose of fitting or training the member in its proper use up to ten business days prior to the member's discharge date. The durable medical equipment must be solely for use in the member's home or community. The provider may not bill for durable medical equipment for the days that the member was receiving training or fitting in the facility. The provider must use the date of the member's discharge from the facility as the date of service on the claim.

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-19
	Transmittal Letter DME-20	Date <del>09/19/98</del> 08/01/08

(D) Delivery Service or Shipping Service.

(1) For DME delivered to a member by a delivery or shipping service, the DME provider is responsible for maintaining in the member's record a copy of the delivery services tracking slip attached to the provider's shipping invoice. The shipping invoice must include:

- (a) the name of the member;
- (b) the quantity of the supply delivered;
- (c) a detailed description of the item(s) delivered including the brand name and, if applicable, the serial number; and
- (d) the delivery service's package identification number.

(2) The delivery or shipping service's tracking slip must refer to each package delivered, the delivery address, and the corresponding package identification number assigned by the delivery service. The date of service on the claim must match the shipping date. The member or the member's designee must sign for the DME in accordance with 130 CMR 409.419(A).

(E) Refills.

(1) For DME provided as refills to an original prescription, the provider must contact the member or the member's designee no later than five business days before shipping or delivering the refill to ensure that the refill is necessary and to confirm any changes to the order. If the member or designee declines a delivery, the provider must not make the delivery and must not submit a claim to the MassHealth agency for the item(s).

(F) MassHealth does not allow automatic deliveries. DME that is delivered to a member on a recurring basis must meet 130 CMR 409.419(E).

(G) For items picked up by the member or delivered to the member's home by the DME provider, the date of service is the date the DME was picked up by or delivered to the member.

(H) The DME provider responsible for the delivery of the DME is also responsible for instructing the member on the use of the DME.

409.420: Repairs to Durable Medical Equipment

(A) Prescription Requirements. MassHealth does not require a prescription or a letter of medical necessity for the repair of durable medical equipment that the MassHealth agency previously determined to be medically necessary for the member.

(B) Repairs of Purchased Durable Medical Equipment. When a repair service for purchased durable medical equipment requires removing the equipment from a member's home, the provider must supply, on a rental basis, properly working substitute equipment that is comparable in most respects to the equipment to be repaired. Rental of substitute equipment is covered by MassHealth in accordance with rates established by DHCFP until repair to the equipment is complete and the original equipment is returned to the member.

(C) Repairs of Rented Durable Medical Equipment. When a repair service for rented durable medical equipment requires removing the equipment from the member's home, the provider must supply the member with properly working substitute equipment that is comparable in most respects to the equipment to be repaired. Providers may continue to bill a rental fee in accordance with rates established by DHCFP, but no extra rental charge is allowed for this substitute equipment.

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-20
	Transmittal Letter DME-20	Date <del>09/19/98</del> 08/01/08

(D) Provider Responsibility. The DME provider who submits a claim to the MassHealth agency for repair of durable medical equipment is responsible for:

- (1) ensuring quality of workmanship and parts;
- (2) ensuring that the repaired equipment is in proper working condition;
- (3) taking advantage of all manufacturer warranties; and
- (4) complying with the requirements of the Wheelchair Lemon Law (M.G.L.c. 93 § 107) and any other applicable provisions of federal and state laws pertaining to the service provided.
- (e)
- (5) providing the member with regular updates regarding the status of the repairs and the expected delivery date of the equipment being repaired.
- (6) responding in a timely fashion to a member's complaint regarding the repair of the equipment.

(130 CMR 409.421 through 409.426 reserved)

#### ~~409.420: Adjusted Acquisition Cost~~

~~Adjusted acquisition cost is defined in 130 CMR 409.402.~~

~~(A) For purposes of 130 CMR 409.000, the term "discount" means any remuneration or reduction of payment of any kind, whether direct or indirect, actually realized by the provider. Any provider who fails to disclose and pass on any such discounts to the Division may be subject to civil and criminal penalties, including imprisonment, in accordance with state and federal laws M.G.L. c. 118E, s. 41, and 42 U.S.C. sec. 1320a-7b(b)(3)(A).~~

~~(B) Except where the manufacturer is the provider, the adjusted acquisition cost must not exceed the manufacturer's current wholesale price, and must be evidenced by the purchase price of the equipment listed on a copy of the supplier's invoice. Where the manufacturer is the provider, the adjusted acquisition cost must not exceed the actual cost of manufacturing the item(s). Those manufacturing costs may include only the cost of raw materials, labor, and overhead.~~

~~(C) If the equipment has not been purchased by the provider at the time of the prior authorization request, a quote reflecting the absolute lowest price of the item may be substituted for the receipted invoice. The quotation must be on the manufacturer's letterhead or form and must be addressed to the provider.~~

~~(D) Where the manufacturer is the provider of any item covered under 130 CMR 409.000, the manufacturer must submit documentation that demonstrates to the Division's satisfaction the actual cost of manufacturing the item, as set forth in 130 CMR 409.420(B).~~

~~(E) The actual receipted invoice must be placed in the member's records. This record must be maintained and available to the Division pursuant to 130 CMR 409.434 and 450.205.~~

#### ~~409.421: Purchase of Durable Medical Equipment and Medical/Surgical Supplies (Excluding Customized Equipment)~~

~~(A) Payment to a provider for the purchase of DME and medical/surgical supplies is the lowest of:~~

- ~~(1) the provider's usual and customary charge to the general public;~~
- ~~(2) the adjusted acquisition cost of the item plus a markup not to exceed:~~

~~50 percent for any item whose adjusted acquisition cost is less than \$25.00;~~

~~(a)~~

~~(b) 45 percent for any item whose adjusted acquisition cost is \$25.00 or greater and less than \$100.00;~~



<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-21
	<b>Transmittal Letter</b> DME-20	<b>Date</b> 09/19/9808/01/08

~~(c) 40 percent for any item whose adjusted acquisition cost is \$100.00 or greater and less than \$200.000;~~

~~(d) 35 percent for any item whose adjusted acquisition cost is \$200.00 or greater and less than \$300.000; or~~

~~30 percent for any item whose adjusted acquisition cost is \$300.00 or greater; and (e) the fee set forth in the schedule of maximum allowable fees that may be adopted by the~~

~~Division as an amendment to these regulations.~~

~~(B) Payment for the following is included in the fee calculated in accordance with 130~~

~~CMR 409.421(A):~~

~~(1) 1 all accessories required to complete the initial set up;~~

~~(2) 2 delivery of equipment to the inside of the member's residence and, when appropriate, to the room in which the equipment will be used;~~

~~(1) installation and/or set up of the equipment;~~

~~(3)~~

~~instruction of the member in the safe use of the equipment;~~

~~(2) removal of the equipment; and~~

~~(3) necessary adjustments to the completed equipment for six months after the initial date of service.~~

~~DME and medical/surgical supplies that are retail stock items must be:~~

~~(C)~~

~~(1) clean (sterilized when appropriate);~~

~~in proper working condition;~~

~~(2)~~

~~(3) free from defects; and~~

~~(4) new and unused at the time of purchase, except for redeemed equipment.~~

~~(D) When a member ceases to need DME purchased for the member by the Division, the member or the member's estate must promptly notify the provider. The provider must recover such equipment to determine if it is redeemable under 130 CMR 409.421(D)(2). Recovery of such equipment is mandatory for the first three years after purchase, but optional thereafter.~~

~~The Division will send an equipment recovery notice to the provider with the approved prior authorization form for purchased equipment. The provider in turn must deliver such notice to the member when the provider delivers equipment that the Division has purchased.~~

~~(1) If the equipment is redeemable, the provider must send a check, payable to the Commonwealth of Massachusetts, to the Division of Medical Assistance. Redeemable equipment is defined as equipment that:~~

~~(a) is no longer needed by the member;~~

~~(b) has a current adjusted acquisition cost, as defined at 130 CMR 409.402, of more than \$400.00 and has been purchased by the Division within the last three years; and~~

~~(c) the provider determines upon inspection to be resaleable or returnable to the provider's inventory, after appropriate reconditioning.~~

~~(3) For redeemable equipment, the amount remitted to the Division must conform to the following redemption schedule:~~

~~(a) within one year from the date of purchase—30 percent of current adjusted acquisition cost;~~

~~(b) within two years from the date of purchase—20 percent of the current adjusted acquisition cost; and~~

~~(c) within three years from the date of purchase—15 percent of the current adjusted acquisition cost.~~

~~(4) If the provider determines that the equipment is not redeemable, the provider must send a letter to the Division's Delivery Systems Unit within 30 days after the equipment is recovered, stating~~

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-22
	<b>Transmittal Letter</b> DME-20	<b>Date</b> 09/19/9808/01/08

~~that the equipment is not redeemable. The letter must include the provider's name, the member identification number, the type of equipment, the date of the determination, and a brief statement of the reason the equipment is not redeemable.~~

~~409.422: Purchase of Customized Durable Medical Equipment, Special Adaptive Mobility Systems, and Special Adaptive Mobility System Add-Ons~~

- ~~———— (A) ——— (1) Payment to a provider for the purchase of customized DME is the lower of:~~
  - ~~———— (a) the provider's usual and customary charge to the general public; or~~
  - ~~———— (b) the fee determined by individual consideration (see 130 CMR 409.426).~~
- ~~———— (2) Payment to a provider for the purchase of special mobility systems and special adaptive mobility system add-ons is the lower of:~~
  - ~~———— (a) the provider's usual and customary charge to the general public less the first \$500, which is the responsibility of the nursing facility as provided for in 130 CMR 456.414; or~~
  - ~~———— (b) the fee determined by individual consideration (see 130 CMR 409.426) less the first \$500, which is the responsibility of the nursing facility as provided for in 130 CMR 456.414.~~
- ~~———— (B) Payment for the following is included in the fee calculated in accordance with 130 CMR 409.422(A):~~
  - ~~———— (1) all accessories required to complete the initial set up;~~
- ~~———— (C) Customized DME, special adaptive mobility systems, and special adaptive mobility system add-ons must be:~~
  - ~~———— (1) clean (sterilized when appropriate);~~
  - ~~———— (2) in proper working condition;~~
  - ~~———— (3) free from defects; and~~
  - ~~———— (4) new and unused at the time of purchase, except for redeemed equipment.~~
- ~~———— (D) When required by the Division, the provider must furnish positive evidence that the medical needs of the member could not be met with retail stock equipment at a lower cost.~~
- ~~———— (E) When a MassHealth member ceases to need DME, special adaptive mobility systems, and special adaptive mobility system add-ons purchased by the Division, the member, the skilled nursing facility where the member resides, or the member's estate must notify the provider. The provider must recover such equipment to determine if it is redeemable under 130 CMR~~

~~409.422(E)(2). Recovery of such equipment is mandatory for the first three years after purchase, but optional thereafter:~~

- ~~———— (1) The Division will send an equipment recovery notice to the provider with the approved prior authorization form for purchased equipment. The provider in turn must deliver such notice to the member when the provider delivers equipment that the Division has purchased.~~
- ~~———— (2) If the equipment is determined to be redeemable by the provider, the provider must send a check, payable to the Commonwealth of Massachusetts. Redeemable equipment is defined as equipment that:~~
  - ~~———— (a) is no longer needed by the member;~~
  - ~~———— (b) has a current adjusted acquisition cost, as defined at 130 CMR 409.402, of more than \$400.00 and has been purchased by the Division within the last three years; and~~
  - ~~———— (c) the provider determines upon inspection to be resalable or returnable to the provider's inventory, after appropriate reconditioning.~~
- ~~———— (3) For redeemable equipment, the amount remitted to the Division must conform to the following redemption schedule:~~
  - ~~———— (a) within one year from the date of purchase — 30 percent of current adjusted acquisition cost;~~

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-23
	Transmittal Letter DME-20	Date <del>09/19/98</del> 08/01/08

~~(b) within two years from the date of purchase—20 percent of current acquisition cost;~~

~~(c) within three years from the date of purchase—15 percent of current adjusted acquisition cost.~~

~~(4) If the provider determines that the equipment is not redeemable, the provider must send a letter to the Division's Delivery Services Unit within 30 days after the equipment is recovered,~~

~~stating that the equipment is not redeemable. The letter must include the provider's name, the member identification number, the type of equipment, the date of the determination, and a brief statement of the reason the equipment is not redeemable.~~

~~(F) The Division will pay for a replacement of a member's current mobility system only when:~~  
~~(1) the cost of repairing the current mobility system will exceed the value of the current system; or~~  
~~(2) the member's condition has changed enough to render the current mobility system ineffective.~~

#### ~~409.423: Rental of Durable Medical Equipment~~

~~(A) The monthly rental payment for DME is the lowest of:~~

~~(1) one sixth of the adjusted acquisition cost of the equipment for the first six months and one twelfth of the adjusted acquisition cost of the equipment for each month after the first six months;~~

~~(2) the provider's usual and customary rental rate and terms to the general public;~~

~~(3) the fee set forth in the schedule of maximum allowable fees that may be adopted by the Division as an amendment to these regulations; or~~

~~(4) the fee determined by individual consideration (see 130 CMR 409.426).~~

~~(B) Payment for the following is included in the fee calculated in accordance with 130 CMR 409.423(A):~~

~~(1) the cost of maintenance, service, and repair of the equipment as needed, including replacement of defective parts;~~

~~(2) the cost of all accessory equipment and disposable items necessary for the proper functioning and use of the rented equipment;~~

~~(3) delivery of equipment to the inside of the member's residence and, when appropriate, to the room in which the equipment will be used;~~

~~(4) installation and/or set up of the equipment; and~~

~~(5) instruction of the member and/or caregiver in the safe use of the equipment.~~

~~(C) DME that is rented on a monthly basis must be:~~

~~(1) clean (sterilized when appropriate); and~~

~~(2) in proper working condition.~~

#### ~~409.424: Purchase of Rental Durable Medical Equipment~~

~~The Division at its discretion may purchase at the following rates of payment DME that is being provided on a monthly rental basis to a member:~~

~~(A) If the Division exercises the option to purchase the equipment within three months from the date of delivery of the equipment, 70 percent of the total rental payments will be applied toward the maximum allowable purchase price computed in accordance with 130 CMR 409.421(A).~~

~~(B) If the Division exercises the option to purchase the equipment any time after three months from the date of delivery of the equipment, 70 percent of the first three monthly rental payments~~

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-24
	Transmittal Letter DME-20	Date <del>09/19/98</del> 08/01/08

~~and 50 percent of all subsequent monthly rental payments will be applied toward the maximum allowable purchase price computed in accordance with 130 CMR 409.421(A).~~

#### ~~409.425: Repair Services for Durable Medical Equipment~~

~~———— (A) All repair services are priced on an individual consideration basis as described in 130 CMR 409.426.~~

~~(B) Whenever a repair service for purchased DME requires removing the equipment from the residential setting, the provider must supply, on a rental basis, properly working substitute equipment comparable in all respects to the equipment to be serviced. The daily rental fee is one-thirtieth of the monthly rental fee calculated in accordance with 130 CMR 409.423(B). No payment for the rental substitute equipment is made for any day following the fifth business day after the date of removal of the equipment from the residence, unless the provider obtains prior authorization from the Division.~~

~~———— (C) Whenever a repair service for rented DME requires removing the equipment from the residential setting, the provider must supply properly working substitute equipment comparable in all respects to the equipment to be serviced. No extra rental charge is allowed for this substitute equipment.~~

~~———— (D) Repairs involving three or more hours of labor are manually reviewed. Manual review requires specific documentation from the provider, including~~  
~~(1) a complete description of the needed repair, including parts;~~  
~~(2) the adjusted acquisition cost of the items as described in 130 CMR 409.420(B) and (C);~~  
~~and~~  
~~(3) the actual number of hours required to complete the repairs.~~

~~(E) When a repair is required more than once in a three month period (excluding wheelchair tires and brakes), payment will be made only if the following documentation is submitted with the claim:~~

- ~~(1) an invoice for the repaired or replaced item;~~
- ~~(2) a detailed description of the circumstances that made the second repair necessary; and~~
- ~~(3) an explanation as to why the repaired or replaced item is not covered under warranty.~~

~~———— (F) The provider of repair services is responsible for the quality of workmanship and parts, and for ensuring that repaired equipment is in proper working condition.~~

~~(G) The provider is responsible for taking advantage of all manufacturer warranties and for honoring Wheelchair Lemon Law (M.G.L. c. 93, s. 107) criteria before submitting claims to the Division for repairs to DME.~~

~~(H) Repairs that will cost more than \$300 for customized mobility systems or for special adaptive mobility systems that are used as backup for a primary mobility system or special adaptive mobility system are reimbursed only after the provider has obtained prior authorization from the Division's Prior Authorization Unit as described in 130 CMR 409.408(A).~~

- ~~(1) The Division pays for repairs to backup customized mobility systems and specialized adaptive mobility systems when both the member's primary and backup mobility systems are so customized that no rental equipment would be comparable.~~
- ~~(2) Documentation describing the extent of the customization of the member's mobility systems must be submitted with the request for repair of the backup system.~~

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-25
	Transmittal Letter DME-20	Date <del>09/19/98</del> 08/01/08

#### ~~409.426: Individual Consideration~~

~~Individual consideration means that the rate of payment for the purchase, rental, or repair of certain DME or for the purchase of certain medical/surgical supplies has not been established by the Division of Health Care Finance and Policy. Such items are identified in Subchapter 6 of the *Durable Medical Equipment Manual* by the designation "(I.C.)" next to the description of the item or service. The rate of payment for an item or service identified as individual consideration is determined by the Division based on the provider's descriptive report of the services provided and he adjusted acquisition cost of materials as defined in 130 CMR 409.420. If necessary, the Division, at its discretion, will submit the service for medical review.~~

~~(130 CMR 409.427 through 409.430 Reserved)~~

#### ~~409.431: Medicare Coverage~~

- ~~(A) When a Medicare covered DME service is furnished to a member who receives Medicare Part B benefits, the Division will always pay up to the Medicare reasonable cost or the Medicaid fee-for-service amount, whichever is lower. The Division's payment for such services is limited to the coinsurance and the deductible amounts. Claims for services furnished to members with Medicare benefits must be submitted in accordance with the instructions in Subchapter 5 of the *Durable Medical Equipment Manual*.~~
- ~~(B) Prior authorization from the Division is not required for Medicare covered services furnished to members who receive Medicare Part B benefits.~~
- ~~(C) If the service that is denied by Medicare normally requires prior authorization from the Division, then the provider is required to obtain prior authorization from the Division before requesting payment from the Division. The provider may request prior authorization from the Division before submitting the claim to Medicare.~~

#### ~~409.432: Provider Responsibility~~

- ~~(A) The provider is responsible for making reasonably certain that the DME or medical/surgical supplies furnished are the most cost effective, given the medical need for which they are prescribed and the member's physical limitations.~~
- ~~(B) Before purchasing equipment or supplies, the provider must make a reasonable effort to purchase the item from the least costly reliable source by comparing prices charged by different suppliers for comparable items.~~

#### ~~409.433: Durable Medical Equipment Furnished to Institutionalized Members~~

##### ~~(A) Institutions Licensed as Nursing Facilities~~

- ~~(1) The Division will pay a DME provider for the purchase or repair of customized DME furnished for the personal full time use of a member residing in a nursing facility only if the customization precludes the use of the equipment by subsequent patients in that institution, as determined by the Division.~~
- ~~(2) The Division will pay a DME provider for the purchase of a special adaptive mobility system in accordance with 130 CMR 409.422(A)(2).~~
- ~~(3) The Division will pay a DME provider for the repair of special adaptive mobility systems.~~
- ~~(4) The Division will not pay a DME provider for the purchase, rental, or repair for noncustomized DME or for any mobility system of the type classified as K0001 through K0003 in Subchapter 6 of the *Durable Medical Equipment Manual*, but will pay a DME provider for the purchase or repair of a special adaptive mobility system add-on to such a mobility system.~~

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-26
	Transmittal Letter DME-20	Date <del>09/19/98</del> 08/01/08

~~(5) The Division will not pay for medical/surgical supplies that are furnished to a member residing in a nursing facility.~~

~~(B) Institutions Licensed as Hospitals, Chronic Hospitals, or Rehabilitation Hospitals. The Division will not pay a DME provider for the purchase, rental, or repair of DME, nor for medical/surgical supplies furnished to a hospitalized member, except for DME that is prescribed primarily for the home use of a member after discharge. The member's discharge plan and date must be documented prior to the purchase, rental, or repair of the prescribed item.~~

~~(C) Institutions Certified and Licensed as Intermediate Care Facilities for the Mentally Retarded (ICF/MR) with 16 or More Beds.~~

~~(1) The Division will pay a DME provider for the purchase or repair of customized DME furnished for the personal full-time use of a member residing in a state school only if the Division determines that the customization precludes the use of the equipment by subsequent patients in that institution.~~

~~(2) The Division will not pay a DME provider for the purchase, rental, or repair of noncustomized DME, nor for medical/surgical supplies furnished to a member residing in a state school.~~

~~(D) Rest Home.~~

~~(1) The Division will pay a DME provider for the purchase or repair of DME furnished to a member residing in a rest home, subject to the conditions and limitations set forth in 130 CMR 409.000.~~

~~(2) The Division will pay a DME provider for medical/surgical supplies furnished to a member residing in a rest home.~~

#### 409.434: Recordkeeping Requirements

~~The provider must keep a record of all DME, repair services, and medical/surgical supplies furnished to a member for at least four years following the date of service. This record must include the following:~~

~~(A) a physician's prescription for all rentals and purchases;~~

~~(B) a copy of the approved prior authorization request for all equipment, supplies, or services requiring prior authorization;~~

~~(C) an acknowledgment of receipt, signed by the member or the member's representative, of prescribed equipment or supplies, that includes:~~

~~(1) the date of receipt of equipment or supplies;~~

~~(2) the condition of the equipment or supplies (for example, whether it is in proper working order, damaged, etc.);~~

~~(3) the manufacturer, brand name, model number, and serial number of the equipment or supplies;~~

~~(4) whether the item was purchased or rented by the Division;~~

~~(5) for repair services, a complete description of the service, including the manufacturer, brand name, model number, and serial number of the repaired item; and~~

~~(6) next to the signature, an explanation of the representative's relationship to the member by the individual acknowledging receipt. This individual cannot be associated with either the provider or the delivery service.~~

~~(a) For routine delivery of supplies, the member must acknowledge receipt at least once monthly.~~



<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-27
	<b>Transmittal Letter</b> DME-20	<b>Date</b> 08/01/08

~~(b) A signature stamp may be used by or on behalf of a MassHealth member whose disability inhibits the member's ability to write. A signature stamp may be used only by the member or the member's representative, provided that the stamp is used by the member in his or her normal course of conducting business. A signature stamp cannot be used by anyone associated with either the provider or the delivery service;~~

~~(D) an invoice showing the cost to the provider of the materials (if the provider is not the manufacturer of the materials);~~

~~(E) documentation demonstrating the cost of manufacturing the item provided (if the provider is the manufacturer); and~~

~~(F) copies of written warranties.~~

~~(130 CMR 409.435 through 409.439 Reserved)~~

~~409.427: Payment for DME.~~

~~Providers of DME must accept MassHealth payment in full for DME according to the rates and regulations established by DHCFP at 114.3 CMR 22.00. Payments are subject to the conditions, exclusions, and limitations set forth in these regulations and in 130 CMR 450.000.~~

~~409.440: Medical Necessity Criteria~~

~~— The following requirements must be met before the Division will approve a service for reimbursement. (A) For services requiring prior authorization, the provider must submit with the~~

~~prior authorization request documentation showing that the medical necessity criteria, set forth in 130 CMR 409.440 through 409.446, have been met.~~

~~(B) For services that do not require prior authorization, the provider must keep the documentation of medical necessity with the member's records.~~

~~409.441: Pressure Reducing Support Surfaces: Group One~~

~~(A) Definition of Service. Group one pressure reducing support surfaces are: ———~~

~~(1) nonpowered pressure reducing mattress overlays designed to be placed on top of a ——— standard hospital or home mattress;~~

~~(2) nonpowered pressure reducing mattresses; or~~

~~(3) powered pressure reducing mattress overlay systems (alternating pressure or low airloss).~~

~~(B) Requirements for Coverage.~~

~~(1) The member must meet the criterion listed in 130 CMR 409.441(B)(2)(a); or~~

~~(2) The member must meet the criteria listed in 130 CMR 409.441(B)(2)(b) or (c) and at least one of the criteria listed in 130 CMR 409.441(B)(2)(d) through (g):~~

~~(a) complete immobility (i.e., patient cannot change body position without assistance);~~

~~(b) limited mobility (i.e., patient cannot independently change body position significantly enough to alleviate pressure;~~

~~(c) any stage pressure ulcer on the trunk or pelvis;~~

~~(d) impaired nutritional status;~~

~~(e) fecal or urinary incontinence;~~

~~(f) altered sensory perception; or~~

~~(g) compromised circulatory status.~~

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-28
	<b>Transmittal Letter</b> DME-20	<b>Date</b> 08/01/08

~~(C) Related Clinical Information. Patients needing pressure-reducing support surfaces must have a care plan that has been established or authorized by the patient's physician. This care plan must be documented in the patient's medical records and must include the following:~~

- ~~(1) education of the patient and caregiver about the prevention and/or management of pressure ulcers;~~
- ~~(2) regular assessment by a nurse or physician;~~
- ~~(3) appropriate turning and positioning;~~
- ~~(4) appropriate wound care (for a stage II, III, or IV ulcer);~~
- ~~(5) appropriate management of moisture/incontinence; and~~
- ~~(6) nutritional assessment and intervention consistent with overall plan of care.~~

~~(D) Reasons for Noncoverage. When the medical necessity criteria set forth in 130 CMR 409.441(B) for a group one overlay or mattress are not met, coverage will be denied as not medically necessary unless there is documentation otherwise justifying the medical necessity for the item in the individual case. The Division will determine if the documentation presented satisfies the requirement of medical necessity.~~

~~(E) Documentation Required. The following documentation is needed for the Division to determine medical necessity:~~

- ~~(1) a written prescription pursuant to 130 CMR 409.407;~~
- ~~(2) a prior authorization request pursuant to 130 CMR 409.408; and~~
- ~~(3) documentation of the patient's medical condition, pursuant to 130 CMR 409.441(B)(2).~~

~~409.442: Pressure Reducing Support Surfaces: Group Two~~

~~(A) Definition of Device. Group two pressure-reducing support surfaces are:~~

- ~~(1) powered pressure-reducing mattress (alternating pressure or low airloss);~~
- ~~(2) semi-electric or total electric hospital bed with fully integrated powered pressure-reducing mattress; or~~
- ~~(3) nonpowered, self-adjusting pressure-relief system.~~

~~(B) Requirements for Coverage.~~

- ~~(1) The member must meet one of the following criteria:~~
  - ~~(a) The member must meet the criteria listed in 130 CMR 409.442(B)(1)(c)(i), (ii), and (iii); or~~
  - ~~(b) The member must meet the criterion listed in 130 CMR 409.442(B)(1)(c)(iv); or~~
  - ~~(c) The member must meet the criteria listed in 130 CMR 409.442(B)(1)(c)(v) and (vi):~~
    - ~~(i) multiple stage II pressure ulcers located on the trunk or pelvis;~~
    - ~~(ii) participation in a comprehensive ulcer treatment program for at least the past month that has included the use of an appropriate group one support surface or an appropriate group three support surface for a healing wound;~~
    - ~~(iii) ulcers that have worsened or remained the same over the past month;~~
    - ~~(iv) large or multiple stage III or IV pressure ulcer on trunk or pelvis;~~
    - ~~(v) recent myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis (surgery within the past 60 days); or~~
    - ~~(vi) needing a group two or three support surface immediately prior to a recent discharge from a hospital or nursing facility (discharge within the past 30 days).~~
- ~~(2) Comprehensive ulcer treatment as described in 130 CMR 409.442(B)(1)(c)(ii) above includes:~~
  - ~~(a) education of the patient and caregiver on the prevention and management of ulcers;~~

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-29
	<b>Transmittal Letter</b> DME-20	<b>Date</b> 08/01/08

- ~~(b) regular assessment by a nurse or physician (usually at least weekly for a patient with a stage III or IV ulcer);~~
- ~~(c) appropriate turning and positioning;~~
- ~~(d) appropriate wound care (for a stage II, III, or IV ulcer);~~
- ~~(e) appropriate management of moisture/incontinence; and~~
- ~~(f) nutritional assessment and intervention consistent with the overall plan of care.~~

~~(C) Reasons for Noncoverage.~~

- ~~(1) When the medical necessity criteria set forth in 130 CMR 409.442(B) for a group two overlay or mattress are not met, coverage will be denied as not medically necessary unless there is documentation otherwise justifying the medical necessity for the item in the individual case. The Division will determine if the documentation presented satisfies the requirement of medical necessity.~~
- ~~(2) Continued use of a group two support surface is covered until the ulcer has healed or, if healing does not continue, there is documentation in the medical record to show that:~~
  - ~~(a) other aspects of the care plan are being modified to promote healing; or~~
  - ~~(b) the use of the group two support surface is medically necessary for wound management.~~

~~(D) Documentation Required. The following documentation is needed for the Division to determine medical necessity:~~

- ~~(1) a written prescription pursuant to 130 CMR 409.407;~~
- ~~(2) a prior authorization request pursuant to 130 CMR 409.408; and~~
- ~~(3) documentation of the patient's medical condition, pursuant to 130 CMR 409.442(B).~~

~~409.443: Pressure Reducing Support Surfaces: Group Three~~

~~(A) Definition of Service. Group three pressure reducing support surfaces are air fluidized beds. These are devices employing the circulation of filtered air through silicone coated ceramic beads, creating the characteristics of fluid.~~

~~(B) Requirements for Coverage. The Division will pay for an air fluidized bed only if all of the following criteria are met:~~

- ~~(1) The patient has a stage III (full thickness tissue loss) or stage IV (deep tissue destruction) pressure sore.~~
- ~~(2) The patient is bedridden or chair bound as a result of severely limited mobility.~~
- ~~(3) The air fluidized bed is ordered in writing by the patient's physician based upon a comprehensive assessment and evaluation of the patient after conservative treatment has been attempted. Conservative treatment includes:~~
  - ~~(a) education of the patient and caregiver on the prevention and/or management of pressure ulcers;~~
  - ~~(b) assessment by a physician or nurse at least weekly;~~
  - ~~(c) appropriate turning and positioning;~~
  - ~~(e) use of a group two support surface, if appropriate;~~
  - ~~(e) appropriate wound care;~~
  - ~~(f) appropriate management of moisture and incontinence; and~~
  - ~~(g) nutritional assessment and intervention consistent with the overall plan of care.~~
- ~~(4) The patient must have been on the conservative treatment program for at least one month prior to the use of the air fluidized bed with worsening or no improvement of the ulcer. The~~

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-30
	<b>Transmittal Letter</b> DME-20	<b>Date</b> 08/01/08

~~evaluation must be performed within a week prior to initiation of therapy with the air fluidized bed.~~

~~(5) A trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air fluidized bed system and its problems.~~

~~(6) A physician directs the treatment regimen, and reevaluates and recertifies the need for the air fluidized bed monthly if deemed necessary.~~

~~(7) All other alternative equipment has been considered and ruled out by the physician.~~

~~(C) Reasons for Noncoverage. An air fluidized bed will be denied as not medically necessary under any of the following circumstances:~~

~~(1) The patient has coexisting pulmonary disease (lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions);~~

~~(2) The patient requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering such as plastic wrap or other occlusive material;~~

~~(3) The care giver is unwilling or unable to provide the type of care required by the patient on an air fluidized bed;~~

~~(4) Structural support is inadequate to support the weight of the air fluidized bed system;~~

~~(5) Electrical system is insufficient for the anticipated increase in energy consumption;~~

~~(6) Other known contraindications exist.~~

~~(D) Documentation Required. The following documentation is needed for the Division to determine medical necessity:~~

~~(1) a written prescription pursuant to 130 CMR 409.407;~~

~~(2) a prior authorization request pursuant to 130 CMR 409.408; and~~

~~(3) documentation of the patient's medical condition, pursuant to 130 CMR 409.443(B).~~

#### 409.42844: Augmentative and Alternative Communications Devices (AAC)

~~(A) Definition of Service. Electronic, nonelectronic, or microprocessor-controlled aids, devices, or systems that help a member overcome or ameliorate the communication limitations that preclude or interfere with meaningful communication of messages. Examples include, but are not limited to:~~

~~(1) communication boards or books;~~

~~(2) electrolarynxes;~~

~~(3) speech amplifiers; and~~

~~(4) electronic devices that produce speech or written output.~~

~~(A) Covered Services: AAC devices are defined in 130 CMR 409.402. The AAC device must be a dedicated speech device, used solely by the member who has the severe expressive communication impairment. Examples of AAC devices are:~~

~~(1) communication boards or books;~~

~~(2) electro larynxes;~~

~~(3) speech/ voice amplifiers; and~~

~~(4) electronic devices that produce speech or written input.~~

~~(B) Requirements for Coverage. AAC devices are MassHealth covered-s AAC devices for members with significant expressive communication impairments if they meet the requirement found at 130 CMR 409.4 (B), (C), and (D) when the following conditions are met These impairments include the following conditions:~~

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-31
	<b>Transmittal Letter</b> DME-20	<b>Date</b> 08/01/08

~~(1) apraxia of speech~~the member has a communication disability with a diagnosis of severe dysarthria, apraxia, and/or aphasia as evidenced by documentation from the member's physician.

~~(2) the device has been prescribed by the member's physician and recommended by a licensed speech and language pathologist who is not affiliated with the AAC provider and who has conducted a thorough evaluation of, and has a treatment plan for, the member's condition that includes use of the recommended device.~~

~~(a) The treatment plan must describe the specific components of the AAC services and the required amount, duration, and scope of the AAC services, and include documentation that demonstrates:~~

~~(i) the requested AAC device and the AAC services constitute the least costly form of treatment that will have the comparable effect of overcoming or ameliorating communication limitations that preclude or interfere with the member's meaningful participation in current and projected daily activities;~~

~~(ii) the impairment or disability has caused communication limitations that preclude or interfere with the member's meaningful participation in daily activities;~~

~~(iii) the member is unable to meet communication needs arising in the course of daily activities using other available communication techniques;~~

~~(iv) therapies or treatments, including speech, occupational and/or physical therapy that have been provided to the member;~~

~~(v) a description of the member's cognitive, visual, auditory, language, and motor ability necessary to utilize the selected device;~~

~~(vi) expected functional communication goals; and~~

~~(vii) a plan of care for the use of the device, including anticipated training needs, programming needs, evaluations, etc.~~

~~(C) The provider has obtained prior authorization from the MassHealth agency for the AAC device. The request for a prior authorization request must include documentation in accordance with 130 CMR 409.418 and documentation demonstrating that the conditions in 130 CMR 409.428(B) have been met, including a copy of the member's treatment plan. (2) a prior authorization request pursuant to 130 CMR 409.408; and~~

~~(3) documentation of the patient's medical condition, pursuant to 130 CMR 409.444(B).~~

~~Medical necessity may be established by the following:~~

~~(a) a diagnosis of a significant expressive communication impairment or disability;~~

~~(b) physician documentation that the impairment or disability has permanently caused communication limitations that preclude or interfere with the member's meaningful participation in current and projected daily activities; and~~

~~(c) an assessment of the member's condition and a treatment plan, both performed by a licensed speech/language pathologist independent of the provider.~~

~~(i) The treatment plan must describe the specific components of the AAC devices and the required amount, duration, and scope of the AAC services; and~~

~~(ii) documentation must demonstrate that the requested AAC device and the AAC services constitute the least costly form of treatment that will have the comparable effect of overcoming or ameliorating communication limitations that preclude or interfere with the beneficiary's meaningful participation in current and projected daily activities.~~

~~(D) Trial Period.~~

~~(1) A trial-use period of not more than two months will may be authorized by the Division MassHealth agency to determine if the device requested is appropriate for the member.~~

Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4 Program Regulations (130 CMR 409.000)	Page 4-32
	Transmittal Letter DME-20	Date 08/01/08

(2) The provider must obtain and submit the following documentation in order to receive a trial period with an AAC device:

- (a) a prescription pursuant to 130 CMR 409.407~~16~~16;
- (b) a prior-authorization request pursuant to 409.401~~8~~18;
- (c) an explanation of the type of AAC device to be used by the member, including all necessary components;
- (c) identification of the clinicians or therapists who will assess the trial period; and
- (d) the evaluation criteria specific to the member; that will be used by the clinician or therapist to determine the success or failure of the trial period.

(3) Success of the trial period will be determined by:

~~(a) an current evaluation of the therapeutic benefit of the AAC device completed~~ by a licensed speech/language pathologist experienced in the assessment of AAC services and who is independent of the provider; ~~or~~

~~(b) a 15-20 minute video of the member using the AAC device.~~

(4) After evaluating all appropriate documentation, the ~~Division~~MassHealth agency will decide whether to purchase the equipment or to continue renting up to the purchase price of the device.

(E) Reasons for Noncoverage. The ~~Division~~MassHealth agency will deny coverage of an AAC device where it determines that:

- (1) the criteria set forth in 130 CMR 409.444(C) have not been met; ~~or~~
- (2) after a trial period, the member has failed to demonstrate to the ~~Division's~~MassHealth agency's satisfaction that the device is ~~both useful and beneficial~~medically necessary;
- (3) the requested device is not a dedicated speech device, but is a device capable of running software for purposes other than speech generation, such as devices that can run a word processing package, an accounting program, or perform other non-medical functions.

#### 409.430~~29~~29: Personal Emergency Response System (PERS)

(A) Requirements for Coverage. ~~(1)~~ PERS is indicated for ~~patients~~the personal use of members with medical conditions that cause ~~multiple significant~~multiple significant functional limitations or incapacitation ~~and prevent the member from using other methods of summoning assistance in an emergency such as those that cause difficulties with endurance and ambulation and that contribute to a homebound status.~~

~~(2)~~ In addition to the requirements in 130 CMR 409.445(B)(1), the PERS is available for members who meet all of the following conditions:

(a) have a functioning land line phone that can accommodate a PERS;

~~(a) be physically able to summon help with the PERS unit;~~

(b) live alone or are routinely be alone for extended periods of time such that the member's safety would be compromised without the availability of a PERS unit in the home

(c) are able to independently use the PERS to summon help;

~~(db) be mentally alert understand when and self directing how to appropriately use the PERS;~~

~~(e) have a functioning telephone with a direct line;~~

~~(d) be alone for extended periods or have no regular contacts;~~

(e) be at risk of moving to a more restrictive supervised setting; or are requiring institutional services at least at the nursing facility level, as determined by the Division;

~~(f) be at at significant risk for falls or other medical complications that may result in an~~

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-33
	<b>Transmittal Letter</b> DME-20	<b>Date</b> 08/01/08

~~emergencies-y situation.~~

~~(2) PERS must meet the definition in 130 CMR 409.402 and must include all of the following:~~

~~(a) an in-home communications transceiver;~~

~~(b) a remote, portable activator;~~

~~(c) a central monitoring station with backup systems, staffed by trained attendants 24 hours a day, seven days a week; and~~

~~(d) current data files at the central monitoring station and at each service facility containing pre-established response protocols, and personal, medical, and emergency information for each member served.~~

~~(B) Documentation Required. The following documentation is needed for the Division-MassHealth agency to determine medical necessity:~~

~~(1) a written prescription that is in compliance with 130 CMR 409.40716;~~

~~(2) a prior authorization that is in compliance with 130 CMR 409.4018; an~~

~~(3) documentation by the member's physician of a preexisting history that includes acute exacerbations leading to emergent or urgent care. Prescribing Provider that the member meets the criteria in 130 CMR 409.429(A) and describes the member's medical condition that causes significant functional limitations or incapacitation or the pre-existing history that includes acute exacerbations which may lead to an emergency situation.~~

~~(C) Reasons for Noncoverage. MassHealth does not pay for PERS when the following conditions apply:~~

~~(1) A-The PERS unit is considered a duplication of services and is not covered when the patient already has equipment already available to the member in an meet-emergency needs (e.g., TTY service, emergency call buttons, personal care attendants or other electronic means of calling for help).~~

~~(2) The member has access to help on a 24-hour-per-day, seven-day-per-week basis~~

~~(23) The Division does not cover a PERS unit for conditions that do not characteristically cause acute incapacitation of the member unless the physician documents a preexisting history of acute exacerbations leading to emergency care requirements.~~

~~(D) Replacement. Replacements for loss or damage beyond repair are covered by the manufacturer's warranty.~~

#### 409.446: Enteral Nutrition

~~(A) Definition of Service. Enteral nutrition is defined as supplementation with energy and protein-rich foods for patients on modified consistency diets, the chronically ill with anorexia, and those with chronic inflammatory and malignant disease, using commercially available products that will provide intensive protein and calorie support, when the integrity of the gastrointestinal tract is preserved.~~

~~(B) Requirements for Coverage. Home enteral nutrition is reimbursable in members with a functional gastrointestinal tract who are unable to consume their diet by mouth and have a compromised nutritional status requiring supplementation.~~

~~(C) Reasons for Noncoverage. The Division will not cover home enteral nutrition for members who are underweight but have the ability to meet their nutritional needs orally.~~

~~(D) Documentation Required. The following documentation is needed for the Division to determine medical necessity:~~

~~(1) a written prescription that is in compliance with 130 CMR 409.407;~~



<u>Commonwealth of Massachusetts</u> <u>MassHealth</u> <u>Provider Manual Series</u>  <u>Durable Medical Equipment Manual</u>	<u>Subchapter Number and Title</u> <u>4 Program Regulations</u> <u>(130 CMR 409.000)</u>	<u>Page</u> <u>4-34</u>
	<u>Transmittal Letter</u> <u>DME-20</u>	<u>Date</u> 08/01/08

~~(2) a prior authorization request that is in compliance with 130 CMR 409.408; and~~  
~~(3) documentation by the physician stating the above prerequisites for instituting the above therapy.~~

#### 409.431: Recordkeeping Requirements

The DME provider must keep a record at the service facility for each member. The record must include all purchases, rentals, and repairs of DME provided for each member in accordance with the recordkeeping requirements set forth in 130 CMR 450.205. The provider must make such records available to the MassHealth agency upon request. Payment for services is conditioned upon the complete documentation in the member's record. In addition to fulfilling the requirements of 130 CMR 450.205, the provider must ensure that each member's record includes:

(A) a completed, signed, and dated prescription that meets the requirements set forth in 130 CMR 409.416;

(B) a letter of medical necessity that meets the requirements set forth in 130 CMR 409.417;

(C) a copy of the prior-authorization request submitted to the MassHealth agency (if the request was submitted on paper), including a copy of the MassHealth agency decision;

(D) written confirmation of receipt of the prescribed DME, including refills, signed by the member or the member's designee, that includes:

(1) the date the equipment or medical supplies were delivered to the member;

(2) the manufacturer, brand name, model number, and, if applicable, the serial number of the equipment or medical supplies;

(3) for repair services, a complete description of all repair services, including the manufacturer, brand name, model number, and serial number of the repaired item; and

(4) if the delivery slip is signed by the member's designee, an explanation of the designee's relationship to the member. This individual cannot be associated with either the provider or the delivery service.

(E) a copy of the original invoice showing the cost to the provider of the materials (if the provider is not the manufacturer of the materials);

(F) copies of written warranties and any discounts;

(G) documentation of member's other insurance and any documentation submitted to and received regarding other insurers.

(130 CMR 409.432 through 409.439 Reserved)

#### REGULATORY AUTHORITY

130 CMR 409.000: M.G.L. c. 18, s. 10; M.G.L. c. 118E, s. 4.

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Durable Medical Equipment Manual	<b>Subchapter Number and Title</b> 4 Program Regulations (130 CMR 409.000)	<b>Page</b> 4-34
	<b>Transmittal Letter</b> DME-20	<b>Date</b> 08/01/08

This page is reserved.